

United States Department of Agriculture Animal and Plant Health Inspection Service Plant Protection & Quarantine 4700 River Road Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil

Interstate Movement

Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME: Brian Vaughan **PERMIT NUMBER:** P526P-18-01796 **ORGANIZATION:** Monsanto, Agradis Campus APPLICATION NUMBER: P526-180202-010

ADDRESS: 6650 Nancy Ridge Drive **FACILITY NUMBER:** 3546 San Diego, CA 92121

MAILING ADDRESS: 6650 Nancy Ridge Drive HAND CARRY: No

San Diego, CA 92121 DATE ISSUED: 05/07/2018

PHONE: 619-368-1269 DATE AMENDED: 05/02/2019 FAX: **EXPIRES:** 05/07/2021

6650 Nancy Ridge Drive, San Diego, **DESTINATION:** CA 92121

RELEASE:

Under the conditions specified, this permit authorizes the following: Shipment Origins Originally Collected Regulated <u>Life</u> **Intended Use Culture Designation** Article Stage(s) Colletotrichum Research - Growth Any AK, HI, MP, PR, Originally Collected from infected host material Chamber (lab VI, Continental U.S. Foreign and Domestic and pure cultures included) Locations Research - Growth AK, HI, MP, PR, Fusarium Any Originally Collected from infected host material Chamber (lab VI, Continental U.S. Foreign and Domestic and pure cultures included) Locations Research - Growth AK, HI, MP, PR, Originally Collected from Phytophthora Any infected host material Chamber (lab VI, Continental U.S. Foreign and Domestic and pure cultures included) Locations Pythium Any Research - Growth AK, HI, MP, PR, Originally Collected from infected host material VI. Continental U.S. Foreign and Domestic Chamber (lab and pure cultures included) Locations Rhizoctonia Research - Growth AK, HI, MP, PR, Originally Collected from infected host material Any Chamber (lab VI, Continental U.S. Foreign and Domestic and pure cultures included) Locations Verticillium Any Research - Growth AK, HI, MP, PR, Originally Collected from infected host material VI, Continental U.S. Foreign and Domestic and pure cultures Chamber (lab included) Locations

PERMIT GUIDANCE

Permit Number P526P-18-01796

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Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury (see

http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx for current country/regional listings) for current country listings.

This permit does not authorize importation, interstate movement, and/or environmental release of strains of genetically engineered regulated organisms (created by the use of recombinant DNA technology).

If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.sh tml.

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, or your States Department of Agriculture to ensure proper permitting.

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

This permit authorizes the interstate movement of pure cultures of the listed organisms or host material infected with the listed organisms from various researchers within the United States and its territories to Brian Vaughan at Monsanto in San Diego, California for laboratory and growth chamber research in Containment Facility #3546 (CF#3546).

This permit authorizes the movement of soil associated with plant roots.

- 1. The permit holder must:
 - (a) comply with all requirements and permit conditions,
 - (b) maintain a valid permit so long as the regulated organisms are alive,
 - (c) this permit cannot be assigned or transferred to other persons.
 - (d) permittee must maintain a residence in the United States
 - (e) safeguard and dispose of the regulated organisms during the term of this permit,
 - (f) take all necessary precautions to prevent the unauthorized release of regulated organisms. In the event of an unauthorized release, the permit holder must notify the permit unit,
 - (g) adequately mitigate environmental impacts resulting from unauthorized release of regulated organisms,
 - (h) contain any/all organisms not authorized under this permit,

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WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)



- (i) notify the permit unit of the receipt of unauthorized organisms,
- (j) notify the permit unit if facilities are destroyed or decommissioned for any reason,
- (k) maintain an official permanent work assignment at the address on this permit,
- (l) notify the permit unit in advance of any change in the permit holder's work assignment,
- (m) destroy all regulated organisms prior to departure unless other arrangements are confirmed by the permit unit prior to the permit holder's departure, and
- (n) notify the permit unit of the destruction of regulated organisms.

Notifications to the permit unit must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

- 2. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. Plant pathogen select agents currently listed include: Peronosclerospora philippinensis (Peronosclerospora sacchari), Conothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia solanacearum, Rathayibacter toxicus, Sclerophthora rayssiae, Synchytrium endobioticum, and Xanthomonas oryzae.
- 3. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated organisms authorized under this permit.
- 4. All organisms must be shipped in packages of such materials and/or construction so as to prevent the unauthorized dissemination or release of regulated articles.
- 5. Upon receipt, all packages must be opened within a biosafety cabinet, that meets or exceeds Class II, Type A, in the permit holder's assigned laboratory facilities within CF#3546 to ensure the shipment contains only permitted organisms and is free of contaminants. Cultures must be in sealed containers during transport to or within the permit holder's assigned research facilities.
- 6. Field-collected samples of infected plant material must be bare-root or washed free of soil prior to shipment to the permit holder.

Plant samples deliberately inoculated with these organisms in a controlled environment such as a laboratory, growth chamber, or greenhouse that have been grown in sterilized soil or soilless mix may be shipped to the permit holder with attached soil or growing media.

Samples of infected plant material may be shipped with small amounts of soil with the roots.

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- 7. All packaging materials in contact with organisms and/or contaminants and all un-used and leftover organisms must be sufficiently heat or chemically treated to kill all plant pests and contaminants prior to disposal. (see also Condition #11)
- 8. All research activities, plant inoculations and subsequent disease development must occur in laboratories and/or growth chambers within CF#3546 that have been inspected and found adequate for containment of the organisms received under this permit. Access to laboratories and/or growth chambers must be restricted to authorized personnel.
- 9. Organisms must be maintained or stored in the permit holder's research facilities within CF#3546. All stored organisms must be kept in a locked area with access restricted to authorized personnel.
- 10. A record must be kept of all organisms maintained under this permit. Minimally this record will consist of the name of the organism identified to the lowest taxon possible, the state, where each isolate was collected, and the date the isolate was received. This record will be made available upon request.

11. 1. DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

All waste materials must be treated by one of the follow methods prior to disposal:

Use any of the following, either alone or in combination: 1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes. Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

Any equipment, supplies, tools, secondary shipping containers, packing materials (e.g, ice packs), etc. must be sterilized/sanitized/decontaminated prior to reuse, disposal, or removal from containment.

If using an autoclave the following protocol must be used:

a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15

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psi.

b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal. c. The autoclave must be calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.

OR

The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of Geobacillus stearothermophilus that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the Geobacillus sterothermophilus and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.

2.

As an alternative to the DEVITALIZATION AND WASTE DISPOSAL requirements listed above, devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles

- 12. There is to be no further movement or distribution of organisms within the United States and its territories unless the recipient holds a valid permit for receipt of such organisms.
- 13. All persons working with these organisms must be informed of these permit conditions. Anyone working with these organisms must agree to and sign/ initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/ APHIS but must be readily accessible in the event of an inspection and presented upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

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14. Reporting Requirements:

The permit holder or authorized individual must notify APHIS Plant Protection and Quarantine (PPQ) Pests Pathogens and Biocontrol Permit Branch (PPBP) within 10 working days of the confirmation that an organism is identified as (a) a species new to science, (b) an organism not known to occur in the United States, or (c) a pest managed by an APHIS program (program pest; http://www.aphis.usda.gov/plant_health/plant_pest_info/index.shtml). Include the permit number, the origins and dates of receipt of the samples, and the identified organism. The notification must be sent to USDA/APHIS/PPQ/RPM/PPB, 4700 River Rd., Unit 133, Riverdale, MD 20737, faxed to 301-734-8700 or emailed to Pest.Permits@aphis.usda.gov Attn: Zhaowei Liu, as Word, Excel or pdf documents. Notifications must also be sent to the State Plant Health Director (SPHD) and State Plant Regulatory Official (SPRO) of the state of origin of the specific sample within 10 working days (see

http://www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml and http://www.nationalplantboard.org/member/index.html for contact information).

15. Under the Plant Protection Act, individuals or corporations who fail to comply with these conditions and authorizations, or who forge, counterfeit, or deface permits or shipping labels may receive civil or criminal penalties, and may have all current permits cancelled and future permit applications denied.

END OF PERMIT CONDITIONS

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